Obesity in Adults on Antidepressant Therapy: Project Report

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Abstract

In the United States obesity continues to be a growing issue in the adult population, which is compounded by the fact that many people have had antidepressant therapy at some point in their lives. Health problems such as metabolic syndrome, diabetes, skeleton/joint issues and more can stem from obesity. These comorbid health care problems can increase the costs at the state and federal levels. This paper will examine obesity and its relation to antidepressant therapy in depressed adults that are obese or endeavoring to avoid further weight gain. Research indicates that antidepressant therapies have shown a greater propensity towards weight gain, though few research studies show weight loss. Intervention: 10 minutes of nutritional counseling during office visits. Setting: Family psychiatric clinic in the southwest of the United States. Methods: Data collection process: Depressed adults on antidepressant therapies were randomly selected. Instrumentation: Weight scale, National Literacy Scale, pamphlet (for teaching) and height scale. Data collected was at baseline, 4 weeks and 8 weeks. Outcomes: 14 Participants agreed to the project, 10 completed to the 4-week mark and 4 finished the project to the 8-week mark. 10 female participants and 4 male participants. The remaining 4 participants showed 1.6% reduction in body mass index, which correlated with an increase in nutritional learning from baseline to 8-weeks. Recommendations: Nutritional counseling is a non-pharmacological intervention for achieving and a desired weight, which has shown positive results in varying populations and clinical situations.

Keywords: Antidepressant therapy, obesity, nutritional counseling, depression

Obesity in Adults on Antidepressant Therapy

Obesity is one of the most common healthcare problems faced in the United States today. Obesity is described by the Center of Disease Control and Prevention (CDC) as having a body mass index (BMI) of greater than 30 (CDC, 2019). The body's basal metabolic rate (BMR) is the caloric energy required to maintain its bodily functions at rest. Consuming calories beyond maintenance BMR will result in excess stored adipose tissue on the body (Benton, 2017). Antidepressant therapy has been associated with obesity since their introduction, though no mechanism has been singled out as the responsible mechanism of action. Some suggest it is the depression itself, the western diet or a change in food cravings.

In 2008 the annual healthcare cost of obesity in North American totaled $147 billion; the healthcare cost for people who are obese was $1,429 greater than those of normal weight people. The prevalence of obesity increased from 30.5% to 42.4% in years 1999 to 2018 (CDC, 2020.)

Background and Significance

Most people either know someone currently being treated for or have experienced clinical depression themselves. Depression affects individual's differently though most will experience depressed mood most days, diminished interest/pleasure in activities, significant weight changes, sleep disturbance, psychomotor disturbances, energy loss, feeling of worthlessness or guilt, diminished concentration, and thoughts of death (American Psychiatric Association, 2013). When a depressed person gains weight, this may increase their depressive symptoms. The inverse is also true, when losing weight depressive symptoms can decrease. Patients must be concerned about weight gain as it can lead co-morbid conditions to health issues, such as diabetes, metabolic syndrome and cardiovascular problems (American Heart Association, 2018).

Antidepressant therapy is used facilitate or enhance a sense of well-being and to reduce

patient's depressive symptoms. According to Stahl (2013) antidepressant therapy is used to facilitate a complete remission of depressive symptoms and sustain mood. A common antidepressant therapy is selective serotonin reuptake inhibitors (SSRI's), which works by increasing the serotonin level by stopping some reuptake into the presynaptic cell. This action increases the serotonin level available to bind to the postsynaptic receptor, which makes more serotonin available in the brain (Stahl, 2013).

The beneficial effects experienced by antidepressant therapy are a reduction in depression symptoms, which can have a profound effect on patients' work, social and school-life. According to a study by Delaveau et al., (2016) in depressed patients taking antidepressants had short and long-term positive effects on emotional regulation during self-referential process and anhedonia. The negative side effects of antidepressants are serotonin syndrome, apathy, sexual side effects, weight gain, bleeding (antidepressant can interact with blood thinners such as coumadin and aspirin) and sedation (Delaveau et al., 2016).

According to Aterburn et al., (2016) long-term antidepressant therapy is significantly associated with weight gain at the two-year mark. Coping with weight gain during antidepressant therapy is important so the patient can avoid health problems associated with weight gain. Authors Di Angelantonio et al., (2016) report that keeping the patients BMI in the normal range can prevent one in five deaths that are obesity related issues. According to the World Health Organization, (2017) a normal range BMI is 18.5 to 24.9 kg/m2; and a BMI greater than 24.9 are associated with cancer, coronary artery disease, stroke, and metabolic disorders. The American Heart Association (2019) reports that maintaining a healthy BMI can facilitate proper sleep patterns, alleviate joint pain, increased energy, improve regulation of bodily fluids and blood pressure, and reduced burden on the heart and circulatory system.

Obesity can have a significant influence on the patient's cardiovascular condition including an increased the risk of high blood pressure, cardiovascular disease, hyperlipidemia , and diabetes (Samuel, 2016). The CDC states that 39.8% of the population in the United States is having a BMI greater than 30, which is classified as obese. Furthermore, 11% of the population 12 years and older has been prescribed antidepressants (CDC, 2018). An adult patient receiving antidepressant therapy has a 40% chance of meeting criteria for obesity, which can limit their treatment options (CDC, 2018). Researchers state that elevated BMI levels correlate with higher rates in relapse of depressive symptoms in depressed patients (Jha, et al., 2018).

Some research has yielded positive results of antidepressants effecting patients body weight. Researchers Mansoor et al., (2014) reported during a two-year study of patients on a variety of antidepressant therapies, there were no significant weight gain. According to researchers Dombrowski et al., (2014) a meta-analysis of 45 randomized controlled trials (RCT's), which consisting of 7,788 participants were able to lose weight and maintain their results with behavioral interventions. It is important to note however, these interventions produced small, though statistically significant results (Dombrowski et al., 2014).

In the majority of clinics, the healthcare workers include medical doctors, nurse practitioners, physician assistance and medical assistances. The provider monitors patient's vital signs, height, and weight, which are taken at office visits by the medical assistance. Most clinics do not offer nutritional counseling sessions and have no talk therapy option to help patients cope with the adverse effects of weight gain associated with antidepressants.

The interventions that help individuals cope with obesity and their potential adverse effects will be reviewed here as well. Patients that are depressed are less likely to seek out help in order to cope with the weight gain. During the lifespan of North Americans 60% of have taken

antidepressants for two years or longer and 14% have taken them for 10 years or longer (CDC, 2019). This creates a long timeline of exposure to the drug and for adverse reactions such as weight gain.

Healthy People 2020 created the initiative Nutritional and Weight Status-9 (NWS-9) to establish a goal to lower the nationally percentage of obesity in adults by 10% (Healthy People, 2019). From 2005-2008 the national percentage of obese adults (BMI > 30) was 33.9%, in 2013-2016 the percentage increased to 38.6%. Healthy People 2020 aimed to decrease this national percentage to be 30.5% (Healthy People, 2019). A Meta-analysis conducted by Dombrowski et al., (2014) demonstrated that the participants were able to lose weight with behavioral interventions and able to maintain the weight loss. In another study, patients with a variety of psychiatric diagnosis participated in a behavioral modification plan to change their nutritional habits; after 18 months 18.5% of the intervention group lost greater than or equal to 10% of their BMI, while 7% of the control group lost 10% of their BMI over 18 months (Daumit et al., 2013). While not all of the patients were diagnosed with depression, though all were diagnosed with a psychiatric disorder while participating in this weight loss intervention. The study showed that most patients are capable of weight loss with support and teaching, despite coping with mental illness.

Internal Evidence

Currently, in this clinic, weights and vital signs are recorded during most visits. Weights are not recorded during tele-medicine calls, though most offices have policies that the patient must have one face-to-face office visit per year. The current evidence shows that physical activity and a caloric deficit diet can result in weight reduction in participants while on antidepressant therapy. Though the more elevated the patients BMI over normal range, the

higher their rate of depressive symptoms will be during relapse (Jha, M. et al., 2018). This information could help to motivate some patients in obtaining a healthy BMI and be successful in the treatment of their depression. A psychiatric clinic in the Southwestern US felt an evidenced-based, non-pharmacological, proven intervention for weight management of depressed patients taking antidepressants would be beneficial. Nutritional counseling became one option to explore.

Currently, clinics record weights and vitals during most visits and weights are not recorded for tele-medicine calls, although most offices have policies that the patient must have one face-to-face office visit per year. During a recent observation in a psychiatric office visits five patients had been switched to other antidepressants due to weight gain from the antidepressant, though the previous antidepressant did reduce depressive symptoms. In most clinics' providers document any weight gain during a trial of antidepressant and will continue the medication, while monitoring the patient's weight in future visits. Though if the antidepressant trial begins with the patient with a high BMI and the patient gains weight, the provider will consider switching the antidepressants.

During regular psychiatric office visits, clinical staff have discovered many depressed patients have poor nutritional knowledge, such as, food and drink content, portion size, and poor food choices in general. Staff monitor patients' weight, height and vital signs at in-office appointments and relate to the patient any trends in their weight in comparison to recent visits. Many depressed patients at this clinic report not exercising, though when the medication starts to work the patients state they are more agreeable and motivated for an exercise program. After reviewing national statistics, it is apparent that depressed patients are trending upward with their weight when prescribed antidepressants (Healthy People, 2019). The healthcare provider at this

site are interested in a proven method to help patients cope with this adverse effect. This led to

the PICOT question: In adult patients receiving antidepressant medications (P), how does 15

minutes of nutritional education sessions pre office visit (I) compared to standard of care (C)

effect weight (O) over a two-month period of time (T)?

Evidence Synthesis

Most studies that showed significant results in helping participants to lower BMI's

focused on nutritional counseling, motivational interviewing, weight loss medications and

switching antidepressant medications. According to Arterburn, D., et al (2016) bupropion can be

prescribed and has been shown to reduce weight, though only in non-smoking patients.

Arterburn, D., et al (2016) also reported that bupropion can cause more anxiety and is a poor

selection for patient already coping with anxiety, which is a highly likely symptom associated

with depression. According to Salcedo, MD, B., (2018) 60% of depressed people admit to coping

with anxiety regularly in their life. Prescribing simulating medications like bupropion may help

with weight management, though can result in more anxiety. Though with the correct balance of

medication and therapies, including nutritional counseling, the patient will have more choices of

treatment to cope with their depression and manage their weight.

Pharmacotherapeutic agents for weight-loss such as lipase inhibitors, may result in more

significant weight loss in the short-term studies, though in long term medications were not

shown to be effective. When combined with behavioral interventions, lipase inhibitors proved to

be the most effective treatment, though long-term results of this combined therapy do not exist

(Dombrowski, S. et al, 2014). Four studies (Dayan, P., et al 2018, Dombrowski, S. et al, 2014,

Resnicow, K., et al, 2015, Verhaeghe, N., et al, 2014), showed significant results for nutritional

counseling, especially in long-term studies. Close monitoring and frequent follow-ups are the key to balancing the treatment of weight gain and depressive symptoms.

The major classes of antidepressants are tricyclics, selective serotonin re-uptake inhibitors (SSRIs), the selective serotonin and norepinephrine re-uptake inhibitors (SNRIs) and the monoamine oxidase inhibitors (MAOIs). As these agents act on the body to achieve a desired effect, different classes of antidepressants impact the patient's body weight differently. In a study by Mansoor (2014), patients being treated with citalopram or paroxetine did show increases in body mass index (BMI), while fluoxetine did not result in weight gain and in fact some participants lost weight. According to Arterburn, D., et al. (2016) SNRI's should be a first line defense to treat depression if obesity is already an issue, with SSRI's showing weight gain to varying degrees. Researches King & Ashraf (2018), reported weight gain with their participants in their recent study of tricyclic antidepressants for treatment of trauma.

Search Strategy

The databases searched for this literature review included PsycInfo, Pubmed, CINAHL, and the Cochrane Library. At first, connecting phases were used to describe the population, then interventions and outcome phases were inserted. The initial search began with Pubmed and included keywords: *obesity*, *obesity* and *psychiatric medications*, *weight gain* and *antidepressants*, *weight gain* and *Sertraline*, *weight gain* and *fluoxetine*, *weight management* and *antidepressants*, *nutritional education* and *BMI*, *nutritional education* and *weight*, *patient education* and *BMI*, *diet education* and *obesity*, *nutritional education* and *weight loss* and *obesity*. The search results were reviewed, looking for relevancy to antidepressant therapy, nutritional counseling and obesity.

Keywords and Phrases Searched

All three databases were searched with medical subject heading (MESH) strategies and these keywords: *antidepressive agents* and *depression* or *dysthymia* or *weight gain* and *nutritional counseling* not *pregnant.* The Boolean connector "not" was used to exclude *pregnancy*, "or" was used for *depression* and *dysthymia* to include the population of the PICO question. To yield more specific results a past five-year limitation, human participants and English language parameters were applied. The population is *depressed adults on antidepressant therapy*. The outcome in this PICO is normal BMI or weight loss. This last strategy revealed five results in PubMed, 0 results in CINAHL and 1,178 results in PsychInfo.

Comparing the Three Databases

Antidepressants and *obesity* were searched in all three databases, then limited back to 2014, human beings, English language and research articles. This search yielded 1919 references in Pubmed references, two references in PsychInfo and 326 references in CINHAL. Next search strategy was CINAHL and the keywords used: *antidepressants* and *BMI returned* 73 references, *antidepressants* and *weight gain resulted in* 184 references. In the remaining search in CINHAL *antidepressants* and *obesity* and *weight gain* and *patient education* or *dysthymia* yielded 7,557 results. PsychInfo was searched with keywords: *antidepressants* and *nutritional counseling* yielded 14 references, *antidepressants* and *BMI* 139 references. Next *antidepressants* and *weight loss* and *obesity* were combined and yielded 81 references.

Specific Author and Gray Literature

During this exhaustive search authors of selected studied were searched separately for similar studies on the topic, though no useful studies were obtained when searching by author alone. A search of grey literature was completed and found a QI paper, policy statements, issues papers, and conference proceedings. Though these documents were not specific enough to the

topic or lacked a high level of evidence for this paper. Some of the studies found did not meet criteria due to low level of evidence, not relatable enough to the topic, participant sample or independent variable was too general and high participant dropout rates during the study. Nutritional counseling showing significant results in four of the studies [(Dayan et al, 2018), (Dombroski et al, 2014), (Resnicow et al, 2015), (Verhaeghe et al, 2014)], especially in long-term studies (Appendix A). This was a significant factor in the selection of nutritional counseling as the intervention for this project.

Theoretical Framework

Imogene King developed the Theory of Goal Attainment and it is appropriate for motivating patients to begin nutritional counseling or a weight management program. According to King (2007), the Theory of Goal Attainment has four key concepts: perception, communication, interaction, and transaction. These key concepts where chosen to be part of the transaction process as it also utilizes the nursing method of assessment, diagnose, plan, implement, and evaluate. The overall assumption is that the focus of nursing is humans interacting with their surroundings, which leads to health. Other assumptions made about humans is that they are spiritual, perceiving, social, rational, controlling, sentient, reacting, purposeful, action- oriented and time-oriented. The clinician and patient will make the goal together, if it was not attained, then why not? Implementations of interventions grounded in the Theory of Goal Attainment well help increase treatment effectiveness of weight management in those on antidepressant therapy.

Evidence Based Practice Model

Models are used to guide our decision-making process and give a framework to where the pieces fit inside a complex project of change. The Iowa Model of Evidence Based Practice (EBP)

was used to propose practice change. According to Polit et al. (2008), the Iowa model is a process-oriented model and is widely used in healthcare to implement EBP changes. The Iowa will model was chosen for this clinical problem because it is a multiphase model that addresses process improvement, risk management, external/internal, and financial data. Step one and two of model demonstrates that we identify the problem identification and concludes it is a priority. Step three and four are to form a team and gather baseline data. Step five and six is to synthesize the data and make the decision that there is sufficient research to implement a practice change, which moves to step seven of implementing change. Finally, step eight, evaluate the results and disseminating the finding to staff and patients (Melnyk & Fineout-Overholt, 2011).

For step one and two obesity was described and its importance conveyed to the patient. Step three and four the team was made up of the medical techs, doctoral student and the provider at the site helped gather baseline data. For steps five and six the data, patient weights and pre/posttests, were synthesized and the decision to implement practice change was made. Step seven patients receiving antidepressant therapy and received nutritional counsel to avoid or cope with weight gain. Finally, in step eight, the information will be evaluated, and the results were disseminated to the stakeholder.

Methods

The population for this study was depressed adults currently on antidepressant therapy willing to participate in the project. The setting was an outpatient psychiatric clinic located in the southwestern region of the United States. Selecting the proper patient, setting them up with nutritional counseling and measuring the goals they have chosen were completed. Height and weight are taken with Brecknell HS-300, which is externally calibrated and certificated with Federal Communications Commission (FCC) compliance (FCC, 2017). Staff at the clinic

includes physicians, nurse practitioners and medical technicians that care for both psychiatric and family medicine needs. The inclusion criteria of the proposed project are as follows: currently taking an antidepressant, adult, overweight and or identified by the nurse practitioner caring for them as having the potential for being overweight.

The National Literacy Scale (NLS) [(Diamond, 2004)] was used to measure the patient learning outcomes. The questionnaire addresses with portion sizes as they relate to BMI and weight. The patient's perception terms such as "fat-free" and "calorie free" were explored and clarified. Macronutrient needs of an adult were discussed, such as, appropriate total daily protein intake and calculating fat percentage from a food label. The term "organic food" written on food label is addressed in the form of how it's grown and cost to the consumer. The questionnaire discussed the need for vitamin D and addresses the empty calories of refined sugar.

The 24-item questionnaire assessed basic adult nutritional knowledge that should be acquired by adulthood by way of public and private schools. In order to show the questionnaire's validity a study was conduct, which details the psychometric characteristics of the NLS. According to author Diamond, J. (2007), a cross-sectional study of 341 patients of two primary care clinics showed the NLS has scored acceptable internal consistency of 0.84 by Cronbach's alpha coefficient and supports evidence for construct validity.

Data analysis plan included data collection of weight/BMI, nutritional goals, and National Literacy Scale will be assessed at baseline, the 4- and 8-week mark.

Procedures to project

1. Obtained participants consent.

2. Baseline weight and height was taken with all participants and BMI was calculated.

3. Administer Nutritional literacy Scale (NLS) Pretest. (10 minutes, includes weight and height measurements.

4. Nutritional Counseling was completed with an emphasis on the participant's knowledge deficiencies. During nutritional counseling a pamphlet with nutritional information was given, which included basic nutritional label reading, macronutrients (carbohydrates, fat and protein) and micronutrients (vitamins and minerals).

5. The participates were asked to select a goal to maintain until the next office visit:

   a) Read all food labels from food purchased at the grocery store.

   b) 5 serving of vegetables and fruits will be consumes daily.

   c) Consume 5 to 6 ½ ounces of protein daily based off age & gender.

6. At the one- and two-month period participants were reweighted, their chosen goals assessed and Nutritional literacy Scale (NLS) Post-test was given to assess nutritional knowledge gained through nutritional counseling.

7. Data was analyzed through Intellectus (2020).

8. Result were disseminated to site staff.

Data analysis Plan for this project was a two-tailed paired sample t-test which was conducted to examine whether the mean difference between variables taken at different data collection points. All data was confidential and was stored on secured/encrypted ASU cloud storage with only the Principle Investigator (PI) and Co-principle investigator (Co-PI) to have access to the data. Consent forms were secured at Bayless property in a locked room, separate locked room from the digital patient data in a file cabinet. No audio or video was taken of the participants. Participants' were given an identification number (pick a color and last two digits of their birth year) and the key to decode the identification number. Institutional Review Board (IRB)

approval was granted and the study approval number was: STUDY00010764. No outside

funding or grants were used to complete this project. The budget was funded solely by the

project manager.

Results

Data analysis: A two-tailed paired sample t-test was chosen to determine if there was a

difference between week 4 BMI and week 8 BMI. A significant decrease was observed in the

mean BMI of week 4 to week 8 of 38.65 to 38.05 at a confidence level of 90%. Results observed

between weeks 4 and 8 were the most significant. The mean of baseline weight and the mean of

8-week weight was not significantly different and show $p = .272$, alpha value was set at 0.10.

Nutritional Literacy Scale test was 25 questions of multiple-choice and participants showed a

significant 18% increase in their test scores from baseline to week 8 as demonstrated by two-

tailed paired sample t-test.

The project did show a clinically significant reduction in the participant BMI especially

at the last two data collection points of the project. 14 Participants agreed to the project, 10

completed to the 4-week mark and 4 finished the project to the end or 8-week mark. There were

10 female participants and 4 male participants in the project. The remaining 4 participants

showed 1.6% reduction in BMI's, which correlated with an increase in nutritional learning from

baseline to week 8. The project collected data from 10/11/2019 to 2/12/20. The participants

relayed difficultly with food choices during the holiday period. After the holiday season

participants showed an increase in their nutritional learning and lowered their BMI's (see

Appendix D).

Discussion

Some barriers/challenges that were incurred during the project were that participants lack motivation and the holiday season. The project mostly took place during the holiday season, in which participants relayed difficultly with food choices and delayed or decreased physical activities. After the holiday season participants showed an increase in their nutritional learning and were able to lower their BMI. Participant motivation was a strong factor and was assessed during nutritional counseling. It was found that waiting for the antidepressant to work was best as the participant appeared more agreeable to the project and nutritional counseling.

The project findings appeared the mimic those found during the literature search with behavior modification and education reducing BMI (Dombrowski et al., 2014). Researcher Daumit et al., (2013) showed significant results with a behavioral modification plan and decrease participants BMI over an 18-month period.

Nutritional counseling is a non-pharmacological intervention that employs education and counseling. The advantages of nutritional counseling are the development of a healthy lifestyle to avoid the adverse effects of weight gain. Having the option to talk with a nutritional counselor empowers the patient and gives them greater control over their treatment. Nutritional counseling encourages a conscientious thought pattern of how the patient to perceives their BMI, food choices and the implications of future weight gain (Dayan, 2018).

Providers can use this opportunity to assess the patients learning and motivation for treatment in general and make adjustments accordingly. This could be an opportunity for the provider to advocate for the patient if they find that patient cannot afford healthy food choices and connect the patient with community support. If nutritional counseling is not showing any substantial benefits, then the patient can easily be withdrawn without any adverse effects to the

patient. The provider may learn that the issue with the patient's weight is not an educational one, though a motivational one, issues at home with food selection or food prep with a diverse household.

Recommendations

Based on a review of the literature obesity issues can be successfully mitigated by offering nutritional counseling to patients, especially those at risk for obesity. Brief nutritional counseling sessions could easily be implemented into most clinical workflow situations. Some providers may not want to offer nutritional counseling and will opt to switch medications, augment treatment with other medications (lipase inhibitors) or continue to monitor patients' weight and mood. Nutrition counseling has shown significantly better long-term results than lipase inhibitors (Dombrowski, 2014). Continuing patient education on antidepressants, weight gain, comorbidities and mood are important so the patient can make educated choices moving forward in their treatment. Positive outcomes from nutritional counseling could be implemented into an existing clinic with little disruption to workflow and minimal monetary investment of the clinical setting. Pamphlets could be made up as a tangible item to give the patient and modern electronic charting systems already have areas for weight, BMI calculations and progress notes for the nutritional counseling. During nutritional counseling sessions the provider can collaborate with the patient's therapist to assess their motivation for losing and maintaining weight loss. Providers should take this intervention as an opportunity to build a more positive alliance with their patients.

Conclusion

Weight gain is significantly associated with antidepressant use, which can lead to increased comorbidities and healthcare costs. Many interventions have yielded weight reduction**,**

though nutritional counseling program can help patients manage their weight while increasing their nutritional knowledge. Discussing the patient body weight goals, reviewing nutrition information and assessing their current shopping and food preparation habits will further strengthen the patient/provider alliance. Other interventions have shown weight reduction, such as, lipase inhibitors, calorie restrictive diets and switching antidepressants. There is significant evidence that nutritional counseling can be a long-term solution that produces positive results without adverse effects. This literature review has revealed nutritional counseling to be the best non-pharmacological evidence-based intervention which providers can proactively implement for weight management.

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     eating in mental health care. *BMC public health*, *14*(1), 856. doi.org/10.1186/1471-2458-

     14-856

Budget Plan

Phase	Activities	Cost	Subtotal	Total
Preparation (Direct cost)	Pamphlet design, prints, and mail pamphlet to participants. (Student provider hrs 5 times $45= $225, 50 copies@ $.60 $30, postage 50@$.70=$35	$290	$290	$290
	Medical Techs hired @ $15/hr 3 hours/week x's 14weeks= 42 hours	$630	$630	$630
	Design & print evaluation tool. Design time 4hrs@$45= $180 Print (50@$.60) = $30	$210	$210	$210
	Travel (50miles@$.30		$15	$15
	Project Lead 20/ week X's 14 weeks (280hrs@$45/hr)	$12,600	$12,600	$12,600
Total Costs				$13,745

Appendix A

Table 1

Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Arterburn, D., et al. (2016). Long-term weight change after initiating second-generation antidepressants. **Funding**: Harvard T.H. Chan School of Public Health **Bias**: None Stated **Country**: USA	Stress Health Process Framework	**Design**: RCT **Purpose**: Investigate long-term weight change in adults on 2nd generations antidepressants in **CG**	Study conducted at Group Health **LOS**=2yrs **N** at start= 4,847 At the 2yr mark, pt Erollment=2,369	**IV**: 2nd Antidepressant selection selective serotonin we uptake inhibitors (SSRI's) **IV Def**: Implementation of 2nd gen. antidepressants **DV1**: Pt.'s wt at 2yr mark w/ Bupropion (non-smoking) **DV2**: Pt.'s wt at 2yr mark w/ Bupropion (smoker) **DV3**: Citalopram patient's wt at 2yr mark. **DV4**: Paroxetine at 2yr mark. **DV5**: Sertraline at 2yr mark **DV6**: Trazodone at 2yr mark.	•Weight scale •BMI	•Linear regression analysis Alpha= 0.05	**DV1**: weight Δ=-8.4 P=0.041 95% CI= -16.5, -0.3 **DV2**: weight Δ= 14.2 P=0.001 95% CI= 3.4, 24.9 **DV3**: weight Δ= 2.9 P=0.032 95% CI= -2.9,8.7 **DV4**: weight Δ=0.3 P=0.96 95% CI= -10.5, 11.1 **DV5**: weight Δ= 5.5 P=0.17 95% CI= -2.4, 13.4 **DV6**: weight Δ=-0.1 P=0.99 95% CI= -13.2,13.0	**S**: •Reliable results when compared to similar studies •Bupropion has potential for 1st line treatment of depressed pts who are overweight •Level 3 evidence •Generizability to providers prescribing antidepressants •**W**: •High dropout rate

Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Dayan, P., et al (2018). A New Clinical Perspective: Treating Obesity with Nutritional Coaching v. Energy-restricted Diets **Funding**: Sport school University of Soa Paulo, Soa Paula, Brazil **Bias**: None Stated **Country**: Brazil	Health Promotion Model	**Design**: Cohort study **Purpose**: Long-term weight loss w/ nutritional counseling vs w/ telephone-based coaching vs Internet-based nutritional group coaching vs Energy restrictive diets.	Study conducted at University of Soa Paulo **LOS**=3yrs **N**= Not given	**IV**: Treat obesity with lifestyle modifications **DV1**: (Intervention group) Pt.'s weight at 3month **DV2**: Pt.'s weight at 3 month (Control group)	•Weight scale	• None stated	**DV1**: (Intervention group) weight Δ at 3 month = 4.2kg overall per pt **DV2**: weight Δ= 1.7kg (Control group)	**Strengths:** •Reliable results when compared to similar studies •Non-pharmacological intervention to Weight loss. •Level 4 evidence cohort studies •Generizability to providers prescribing we loss methods •**Weakness**: •High dropout rate •Not a controlled trial

Key: **AE-** adverse effects, **Alpha-** Level of significance, **BMI-**body mass index **CG-** control group, **CI-** confidence interval, **Def-** definition, **DI-** duration of intervention, **EC-** exclusion criteria, **ES-** effect size, **IC-** inclusion criteria, **IG-**intervention group, **MA-** meta analysis, **MetS-** Metabolic Syndrome **N-** sample size (people), **n-** sample size (studies), **NC-** # of pts in control group, **NI-** # of pts in intervention group, **NCoun-** Nutrition Counsel **p-** alpha value, **Pts-** patients, **QOL-** quality of life, **RCT-** randomized control trial, **S-** strengths, **SA-** statistical analysis **SR-** Systematic Review **W-** weaknesses

Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Di Angelantonio, E., et al. (2016). Body-mass index and all-cause mortality: individual-participant-data meta-analysis of 239 prospective studies in four continents. **Funding**: University of Cambridge, United Kingdom **Bias**: None Stated **Country**: United Kingdom	Behavioral systems and nursing	**Design**: Meta Analysis **Purpose**: Assess relevance to mortality as it relates to body mass index **Participants**: Asia Australia, New Zealand, Europe and North America 189 Studies.	Study conducted at University of Cambridge, United Kingdom **LOS**= In this case the median follow-up was 7-13yrs **N** at start= 3,951,455 participants. -Participants for non-smokers without chronic disease -Reference group was used, which was the largest BMI group. -385, 879 participants died during the studies.	**IV**: All cause mortality rate **IV Def**: Mortality rate as it relates to BMI. Study divided the BMI chart to 9 categories BMI Kg/m² **DV1**: 15-18.5 **DV2**: 18.5-20 **DV3**: 20-22.5 **DV4**: 22.5-25 **DV5**: 25-27.5 **DV6**: 27.5-30 **DV7**: 30-35 **DV8**: 35-40 **DV9**: 40-60	•BMI •Weight scale	•SAS version 9.3 •Inverse variants weighted random effects •Linear regression •Cox Regression model •Hazard ratios calculated •Alpha= 0.05	**DV1**: P=0.0045 95% CI= 1.25-1.49 **DV2**:P=0.28 95% CI= 1.04-1.18 **DV3**:P=0.42 95% CI= 0.97-1.02 **DV4**: P=No data 95% CI= 0.97-1.03 **DV5**: P=0.89 95% CI= 1.04-1.11 **DV6**:P=0.46 95% CI= 1.21-1.35 **DV7**:P=0.20 95% CI= 1.42-1.67 **DV8**:P=0.48 95% CI= 1.59-2.54 **DV9**: P=<0.0001 95% CI= 1.33-4.24	**S**:Reliable results meta-analysis, large study & diverse population. •Results consistent with similar studies •LOE 1 •Generizability to consequences of high BMI •**W**:Asia, Africa and Latin America underrepresented. •BMI does not correlate w/ body composition •Not adjust for ethnicity /socioeconomic status.

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Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Dombrowski, S. et al., (2014). Long term maintenance of weight loss with non-surgical interventions in obese adults **Funding**: FUSE, the Centre for Translational Research in Public Health **Bias**: None Stated **Country**: United Kingdom	Cognitive learning theory	**Design**: SR & MA of RCT **Purpose**: Systematic review with meta-analysis. Medline, PsychInfo, Embase and Cochrane databases were used. W/ 12mo. follow up.	N= 7,788 n= 45 Trails	**IV-** Orlistat (wt loss medication) **DV1-** Behavioral interventions **DV2-** Pt wt w/ tx of both Orlistat and behavioral modification.	•Weight scale •BMI	RevMan 5.1 Risk of bias mothers just to be adequate at Krippendorfs Alpha= 0.82 •Alpha= 0.05	**DV1**-After 12 months–BI's -1.56 kg (95% CI negative 2.27 to -0.86 Kg; 25 comparisons, 2949 pt's) **DV2**-Orlistat combined with BI resulted in -1.8 kg (-2.54 to -1.06; eight comparisons, 1738 pt's) difference compared with placebo at 12 months. BI's show more significant benefits to wt-loss maintenance.	**LOE:** 1 Results can be generalized to practitioners motivating patients to lose wt. **S:** specific eligibility criteria, disagreements in research dissolved by third party researcher. **W**: Some of the diets were poorly described in the research. Studies did not clearly delineate initial wt loss from wt-loss maintenance.

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Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
El Asmar, K., et al., (2018). Early weight gain predicts later weight gain in depressed patients treated with antidepressant **Funding**: None Identified **Bias**: None Identified. Though possible conflict of interest is noted as Bruno Falissard received lecture/consulting fees from ELilly, Bayer, GlaxoSmithKline, Roche. **Country**: France	Behavioral Theory	**Design**: Multi-site RCT. **Purpose**: Data was collected at six University psychiatric departments in France. Patients aged 18 to 65 BMI is less than 25 without MetS. With depression as described by DSM-5	N= 260 Non-overweight, metabolically healthy pt's. During a six-month period, patients were assessed weather early wt gain (>5% after one month) predicts MetS (metabolic syndrome) in depressed patients being treated w/ antidepressants.	**IV**- Depressed patients. **IV Def- Detect** early wt gain as it relates to MetS **1DV**- 5% weight gain at 1 mo. & MetS criteria. **2DV**- 5% weight gain at 3 mos. **3DV**- 5% weight gain at 6 mos. -Plus MetS criteria at 1, 3, 6mo	•Weight scale •Waist circumference (WC), b/p, High triglycerides (TG), LDL, HDL cholesterol, and high fasting plasma glucose (FPG)	• Pearsons Chi-squared test and independent samples t-test were used to assist statistical differences of clinical and sociodemographic characteristics.	24.6% of Pts and early wt gain. Patients with early weight gain had higher MetS incidents **DV1**-16.7% versus 6.9% **(DV2)**: After 3mo. (P= 0.07), 23.8% after 6(**DV3**) mo (P = 0.02) -Among completers n=120), early weight gain was significantly associated with metS.	LOE: level II Generalizable: Practitioners prescribing antidepressants & concerned with MetS should refer pt's that are gaining wt to a general practitioner. **S**: RTC at multiple sites, statistically compensated for wt gain from depression. **W**: Psychiatry's may have taking into account the pt's propensity to gain wt

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Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Kemp, D. E. (2014). Managing the side effects associated with commonly used treatments for bipolar depression. **Funding**: Case Western Reserve University **Bias**: None stated **Country**: USA, Cleveland, OH	Health Promotion Model	**Design**: Multi-site RCT **Purpose**: PubMed database searched for treatment of bipolar depression approve by the FDA.	Study conducted at University of Soa Paulo **LOS**=3yrs **N** at start=15,000 Control Group=186	**IV**-antidepressant therapy **IV Ref**-Second-generation antidepressants/ antipsychotics/ mood stabilizers studied for Weight gain with bipolar depressed pts **DV1**- wt gain with quetiapine 300mg **DV2**- Wt gain quetiapine 600 mg **DV3**- Wt gain olanzapine-fluoxetine	•Weight scale •BMI	• None stated	**DV1**: - Quetiapine 300mg =6.4% wt ^, **DV2**- Quetiapine 600mg=9.4, placebo= 4% wt^, **DV3**- olanzapine–Fluoxetine combo equals 66% wt^.	**LOE: 2 Generalizable:** May consider switching to a lower propensity med for sedation, adverse metabolic effects. **S**: Diverse population. **W**: selection of studies reli eson authors expertise in the area of bipolar depression. RCT trials have limited ability to detect adverse effects that are rare or arise slowly.

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Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Kloiber, S., et al., (2015). Clinical risk factors for weight gain during psychopharmacologic treatment of depression: results from 2 large German observational studies. **Funding**: Max Planck Institute of Psychiatry **Bias**: None stated **Country**: Munich, Germany	Health Promotion Model	**Design**: 2 Cohort studies **Purpose**: Patients had to meet DSM criteria for MDE.	N=703 N2=214 n= 2 2 large clinical Studies conducted separately in Germany.	**IV**- Medication therapy **IV REF**-Wt gain after five weeks in kg's. **DV1** (MARS location) wt- **DV2** (Muenster location) wt	•Weight scale •Hamilton rating scale • BMI	• Linear model and partial correlation with age and gender as covariance. Multivariate regression to discriminate independent effects of variables. IBM SPSS Version 20.	Lower BMI, medication selection severity of depression we're late with wt gain during treatment. **DV1**=BMI change after five weeks^ 0.041 (SD) 0.20 . Wt in 56.3% of pts. **DV2**=BMI change after five weeks^ 0.011 (SD) 0.27.	**LOE:** IV **Generalizable:** Be sensitive to the medication they are prescribing as a different antidepressants have more or less of a propensity to increase wt with pts. **S:** 2 large studies conducted separately **W**: Weight gain could be explained by recovery of appetite and what loss before hospitalization.

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Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Resnicow, K., et al., (2015) Motivational Interviewing and Dietary Counseling for Obesity in Primary Care **Funding**: department of health behavior and health education **Bias**: None Stated **Country**: USA, MI	Health Promotion Model	**Design**: Randomly assigned study **Purpose**: Investigate long-term weight loss with nutritional counseling with PCP and RD 42 practices w/ 3 groups.	• Randomly assigned patients (645) to 3 separate groups 42 practices.	**IV**: Treat obesity with motivational interviewing. **IV Def**: Implementation of nutritional coaching w/ motivational interviewing, **DV1**: treatment as usual (Control group) **DV2**: Pt's receives 4 MI sessions from PCP **DV3**: Pt's receives 4 MI sessions from PCP & 6 from RD.	•Weight scale, BMI, Height W/ stadiometer. •Demographics taken: household income, race, gender, education, and insurance coverage.	• Power of 0.80 and two detailed Alpha =0.05. 25% to 30% attrition rate accounted for at 2yr follow.	All at 2yr follow-up: **DV1**: 1.8% ↓ in BMI, which is not significant **DV2**: 3.8% ↓ In BMI, which is not significant **DV3**: 4.9% ↓ In BMI, which is significant (p=.02)	**S**: Reliable results when compared to similar studies •Non-pharmacological intervention to Weight loss. •**LOE** 2 Randomly study •**Generizability** to providers trying to lower the BMI of pts •**W**: •High dropout rate •Not a controlled trial

Key: **AE-** adverse effects, **Alpha-** Level of significance, **BMI-**body mass index **CG-** control group, **CI-** confidence interval, **Def-** definition, **DI-** duration of intervention, **EC-** exclusion criteria, **ES-** effect size, **IC-** inclusion criteria, **IG-**intervention group, **MA-** meta analysis, **MetS-** Metabolic Syndrome **N-** sample size (people), **n-** sample size (studies), **NC-** # of pts in control group, **NI-** # of pts in intervention group, **NCoun-** Nutrition Counsel **p-** alpha value, **Pts-** patients, **QOL-** quality of life, **RCT-** randomized control trial, **S-** strengths, **SA-** statistical analysis **SR-** Systematic Review **W-** weaknesses

Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Uguz, F., et al., (2015). Weight gain and associated factors in patients using newer antidepressant drugs. **Funding**: **Bias**: None stated **Country**: Turkey	Health Promotion Model	**Design**: RTC **Purpose**: RTC study out of 3 hospitals, adult pts taking antidepressants from 6-36mo.	N= 362 avg age 40.49 n= 1	**IV**-Antidepressant medication in depressed individuals. **IV REF**-different antidepressant medication evaluated for its propensity for weight gain in depressed pts. **DV1**(7%≥ wt gain)- **DV2**(≥ 20% wt gain)-	•Weight scale •Height •BMI •Psychiatric evaluation.	•Multivariate logistic regression analysis used. IBM SPSS. Differences with continuous variables were allies with t-test, X2 test and Fisher exact test. Correlations with final wt were analyzed with Pearson correlation test	-Lower education status, lower BMI, family hx of obesity was predictors of wt gain ≥7%. **DV1**-40.6% **DV2**- 7.2% -Wt difference was statistically significant at (P =.000)	**LOE**: Level 2 **Generalizability:** To providers prescribing antidepressants to depressed patients should consider medication with fewer propensities for wt gain. **S**: 3 hospitals were involved for diversity of pt selection **W:** Small sample size.

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Evaluation Table: Interventions for weight loss during Antidepressant therapy

Citation	Conceptual Framework	Study Design	Sample/ Setting	Major Variables with Definitions	Measurement	Data Analysis	Findings	Strengths & Weaknesses
Verhaeghe, N., et al., (2014). Cost-effectiveness of health promotion targeting physical activity and healthy eating in mental health care. **Funding**: Ghent University special research fund **Bias**: None stated **Country**: Belgium	Behavioral systems and nursing.	**Design**: RTC study **Purpose**: Study over 10 weeks evaluating cost-effectiveness behavioral interventions in pts with mental illness living in shelters in Belgian. 16 different shelter locations.	N= 201 mentally ill pts Selected from 16 Shelter locations in the Belgium area.	**IV-** Psycho-education and behavioral wt management interventions. **IV Ref-** Using educational and behavioral interventions to reduce wt in patients with mental illness. **DV1** men (ICER)- **DV2** women (ICER)-	•Weight scale, BMI, height, Health related quality of life (HRQOL) screening tool, Quality adjusted life years (QALYs), incremental cost effectiveness ratio (ICER).	• Markov decision analytical model use to evaluate cost effectiveness. One-way sensitivity analysis to assess effects of results of varying input parameters. Probabilistic sensitivity analysis for uncertainty of input parameters.	Study concluded that healthy eating and promoting physical activity decreases BMI increasing Quality of life. Decreasing BMI resulted in increasing HRQOL. **DV1**-190,647 **DV2**-266,700 Alpha = 0.05	**LOE:** 2 **Generalizable**: To patients with mental illness to obtain an appropriate BMI. **S**: Large diverse sampling from 16 different locations. **W**: Full pt compliance in the data analysis was the same

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Appendix C

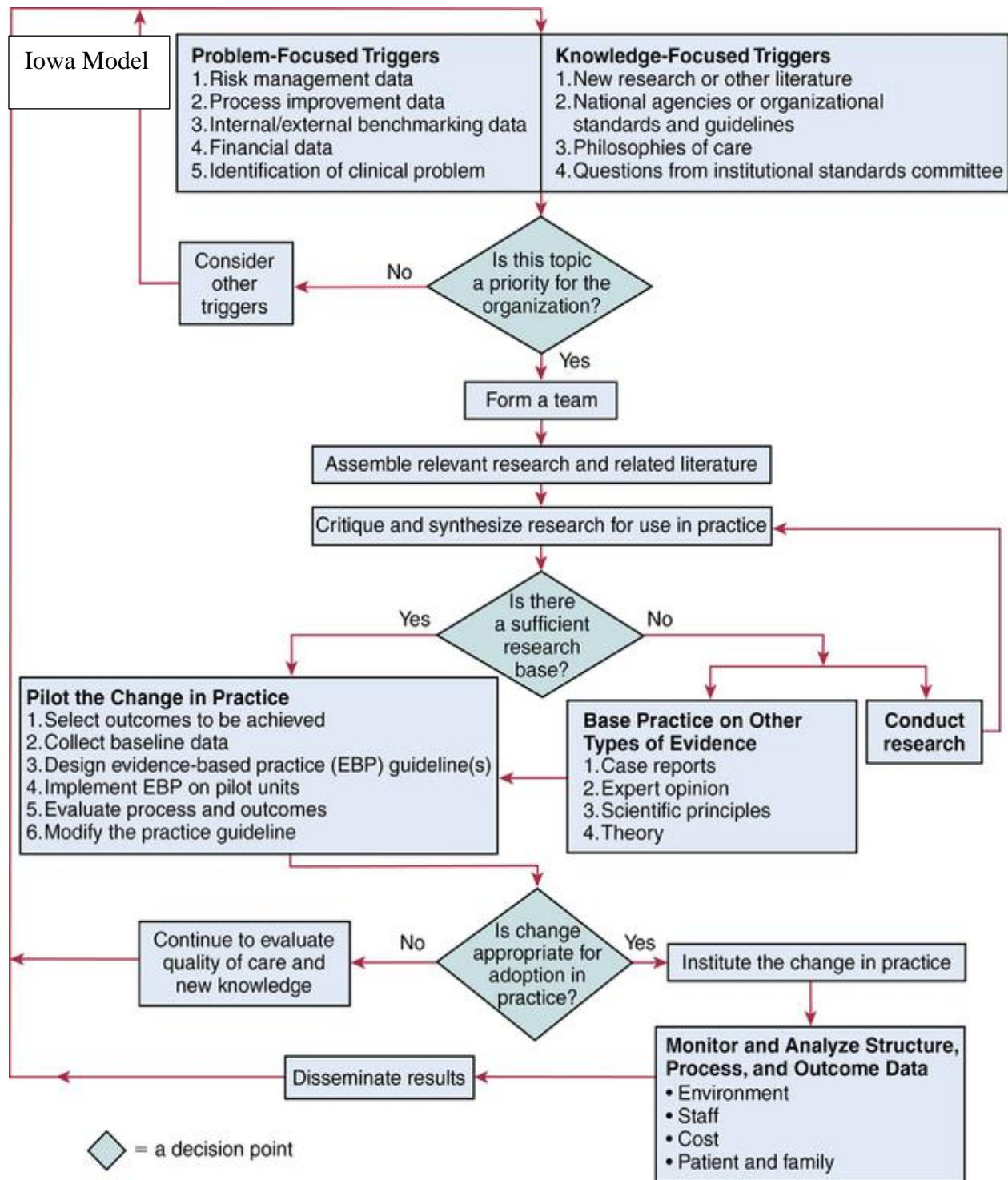*Synthesis Table: Interventions for weight loss during Antidepressant therapy*

Author	Arterburn	Dayan	DiAngelantonio	Dombrowski	El Asamar	Kemp	Kloiber	Resnicow	Uguz	Verhaeghe
Year	2016	2018	2016	2014	2018	2014	2015	2015	2015	2014
Design/Level of Evidence:	RCT/III	Cohort Study/IV	Meta Analysis/I	SR & MA of RCT/I	Multisite RCT/II	Multisite RCT/II	2 Cohort studies/IV	RTC/II	RTC 3 site/II	RCT/II
Study Characteristics										
Demographics	Depressed adults on antidepressants	Obese adults	At risk of chronic DS d/t ↑ BMI	Overweight adults	Normal weight adults w/ depression	Overweight adults	Depressed adults	Overweight adults	Depressed adults	Overweight adults
Setting:	Multi-clinical sites	Multi-clinical sites	Multi-Country/site	Multi-clinical sites	Multi-clinical setting	Multi-Hospital	2 Clinical settings	3 clinic Setting.	3 hospitals	3 hospitals
Sample Size/ # of Studies Included	4,847		189 studies N=3,951,455	7,788	N=120	N=15,000 cg=186	N=703 N2=214		N=362	
Measurement Tools	Weight Scale, BMI Calcultion	Weight Scale	BMI Calcultion	Weight Scale, BMI Calcultion	Weight Scale, MI Calcultion	Weight Scale, BMI Calcultion	Weight Scale, HamiltonScale	Weight Scale, BMI Calcultion	Weight Scale, BMI Calcultion	Weight Scale, BMI Calcultion
Duration of Intervention (hrs)	2yrs	3months	7-13yrs	12 month	1,3 & 6mo. f/u	3yrs	5 weeks	2yrs	6-36mo.	10 month
IV – Interventions										
Calorie deficit										
NutritionCounsel/MI				X				X		X
Bupropion	X									
Bupropion/Smoking	X									
Citalopram	X									
Paroxetine	X									
Sertraline	X									
Trazodone	X									
Phone Coaching										

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Internet group NC		X							
NCoun & Orlist (wt loss medication)				X					
5% wt ↑ at 1 month					X				
5% wt ↑ at 3 month					X				
5% wt ↑ at 6 month					X				
Wt ↑ w/ Antidepressants					X		X		X
Outcomes									
Calorie Deficit		↓~							
NCounsel		↓+		CalorieDeficit				↑+	↑+
Bupropion	↓~								
Bupropion/Smoking	↑+								
Citalopram	↑~								
Paroxetine	↑~								
Sertraline	≠								
MetS w/ early wt ↑					↑+				
Wt ↑ w/ Antidepressants						↑+	↑+		↑+
BMI 15-18.5			↑+						
BMI 18-20			≠						
BMI 20-22.5			≠						
BMI 22.5-25			No data						
BMI 25-27.7			≠						
BMI 27.5-30			↑+						
BMI 30-35			↑+						
BMI 35-40			↑+						
BMI 40-60			↑+						
NCoun & Orlistat				↑+					
5% wt ↑ at 1 month					↑+				
5% wt ↑ at 3 month					↑+				
5% wt ↑ at 6 month					↑+				

Key: **AE-** adverse effects, **Alpha-** Level of significance, **BMI-**body mass index **CG-** control group, **CI-** confidence interval, **Def-** definition, **DI-** duration of intervention, **EC-** exclusion criteria, **ES-** effect size, **IC-** inclusion criteria, **IG-**intervention group, **MA-** meta analysis, **MetS-** Metabolic Syndrome **N-** sample size (people), **n-** sample size (studies), **NC-** # of pts in control group, **NI-** # of pts in intervention group, **NCoun-** Nutrition Counsel **p-** alpha value, **Pts-** patients, **QOL-** quality of life, **RCT-** randomized control trial, **S-** strengths, **SA-** statistical analysis **SR-** Systematic Review **W-** weaknesses

Appendix C

Iowa Model

Problem-Focused Triggers
1. Risk management data
2. Process improvement data
3. Internal/external benchmarking data
4. Financial data
5. Identification of clinical problem

Knowledge-Focused Triggers
1. New research or other literature
2. National agencies or organizational standards and guidelines
3. Philosophies of care
4. Questions from institutional standards committee

Consider other triggers

No ← Is this topic a priority for the organization?

Yes

Form a team

Assemble relevant research and related literature

Critique and synthesize research for use in practice

Is there a sufficient research base?

Yes   No

Pilot the Change in Practice
1. Select outcomes to be achieved
2. Collect baseline data
3. Design evidence-based practice (EBP) guideline(s)
4. Implement EBP on pilot units
5. Evaluate process and outcomes
6. Modify the practice guideline

Base Practice on Other Types of Evidence
1. Case reports
2. Expert opinion
3. Scientific principles
4. Theory

Conduct research

Continue to evaluate quality of care and new knowledge

No ← Is change appropriate for adoption in practice? → Yes

Institute the change in practice

Disseminate results

Monitor and Analyze Structure, Process, and Outcome Data
• Environment
• Staff
• Cost
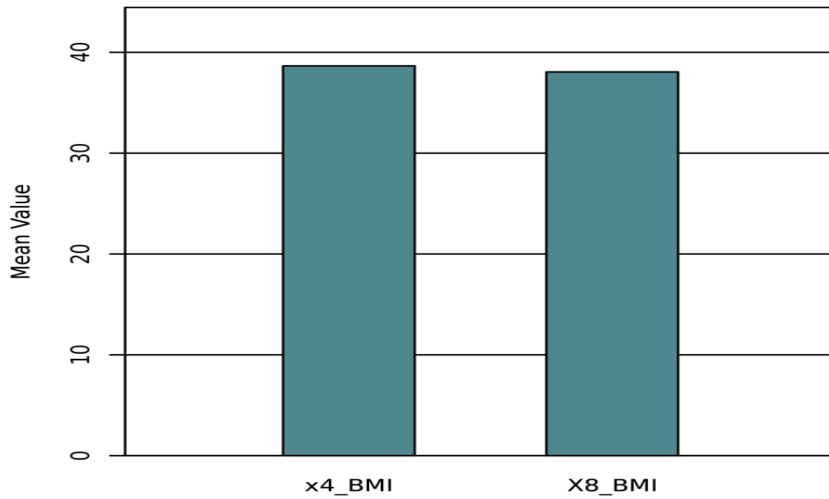• Patient and family

◇ = a decision point

Appendix D

Project Statistics

Bar graph shows a reduction in BMI from 38.65 to 38.05 in week 4 to 8 using a two-tailed paired sample t-test at a confidence level of 90%

Graph A.

Bar graph shows nutritional learning via the NLS increased 18% from baseline to 8 weeks using a two-tailed paired t test.

Graph B.